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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Adreas F. Schaub

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EXAMINER

FRAZIER, BARBARA S

ART UNIT

PAPER NUMBER

1611

NOTIFICATION DATE

DELIVERY MODE

10/09/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/501,984	<b>Applicant(s)</b> SCHAUB, ADREAS F.	
	<b>Examiner</b> BARBARA FRAZIER	<b>Art Unit</b> 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 April 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 12-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

1. Claims 12-16 and 18-23 are pending in this application. Addition of new claim 23 is acknowledged.

#### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. **Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

Claim 15 is vague and indefinite in that the metes and bounds of the phrase “soluble, emulsifiable, dispersible, optionally low molecular weight, optionally biodegradable and/or optionally bioadhesive organic oligomer or polymer formulated as a composition optionally forming a lubricant film or acting as a lubricant” are unclear. The phrase is unclear because it cannot be determined which compounds would read on said limitations for the oligomers or polymers, and Applicant's specification does not provide definition or guidance for which compounds would meet said limitations.

4. **Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

Claim 18 recites the limitation “wherein the composition is in the form of a solution, emulsion, dispersion, oil or hydrogel”. However, the limitations of “solution, emulsion, dispersion, oil” are not supported by claim 12, from which claim 18 depends, since claim 12 is limited to compositions “in the form of a paste, gel, cream, suppository or foam” (see lines 5-6 of claim 12).

***Claim Rejections - 35 USC § 103***

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. The rejection of claims 12, 13, 15, 16, 18, and 19 under 35 U.S.C. 103(a) as being unpatentable over K-Y Jelly is withdrawn in view of Applicant’s arguments.

7. The rejection of claims 12-14 and 18-22 under 35 U.S.C. 103(a) as being unpatentable over Hardy (US Patent 4,981,686) is withdrawn in view of Applicant’s arguments.

**8. Claims 12, 13, 15, 16, and 18-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Leuven (US Patent 4,267,168) in view of Bringloe (US Patent 4,765,478).**

The claimed invention is drawn to a method for reducing the frictional force between an item to be delivered and the birth canal of the mother in human vaginal child birthing, which comprises introducing a composition comprising a physiologically acceptable organic lubricant and no alkali metal salts of metaphosphates, wherein the

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composition is in the form of a paste, gel, cream, suppository, or foam, in an effective amount into the birth canal of the woman (see claim 12).

Van Leuven teaches a composition which is useful as a lubricant to be used during delivery at the time of birth, and does not contain alkali metal salts of metaphosphates (abstract). The composition comprises glycerine, which provides a very soothing action on tender tissue, and therefore acts as an organic lubricant (col. 6, lines 1-2). The composition may be applied to vaginal tissue of the baby's mother (col. 6, lines 52-54). Since vaginal tissue is part of the birth canal, the composition is applied to the birth canal. The composition may also comprise inert stable thickeners, such as hydroxymethylated cellulose, in order to control viscosity (col. 6, 62-65).

Van Leuven does not specifically teach that the composition is in the form of a gel.

Bringloe teaches that hydroxymethyl cellulose is a known gelling agent in topical compositions (see col. 3, lines 46-53).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to formulate the compositions taught by Van Leuven in the form of a gel; thus arriving at the claimed invention. Hydroxymethyl cellulose is a known gelling agent, as taught by Bringloe, and thus one skilled in the art would reasonably expect that the use of hydroxymethyl cellulose in a composition would result in the composition being in the form of a gel. One skilled in the art would have been motivated to add hydroxymethyl cellulose to the composition in order to control viscosity, as taught by Van Leuven, since a thicker (i.e., more viscous) composition

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would result in the lubricant composition adhering better to the wall of the birth canal, thus providing a greater lubricant effect. One would reasonably expect success from the use of hydroxymethyl cellulose as a gelling agent (as taught by Bringloe) in the composition taught by Van Leuven because Van Leuven teaches that hydroxymethyl cellulose may be added to the composition in order to control viscosity.

Regarding claim 13, Van Leuven teaches that glycerine provides skin conditioning and a very soothing action (col. 5, line 58 - col. 6, line 2), and therefore an organic substance (i.e., glycerine) brings about a lubricant effect in the composition, or confers a lubricant effect through formulation of the composition.

Regarding claim 15, Van Leuven teaches the presence of glycerine acting as a lubricant (columns 5 and 6).

Regarding claim 16, Van Leuven teaches that the composition comprises hydroxymethyl cellulose, a known gelling agent, and therefore would form a gel.

Regarding claim 18, Van Leuven teaches that the composition comprises solutions (for example, see Example 1), and therefore reasonably reads on the term "solution".

Regarding claim 19, Van Leuven teaches that the lubricant glycerine is present from 4 to 10% (col. 5, lines 58-59 and claim 1).

Regarding claims 20-22, Van Leuven teaches that the composition comprises the biocidal agents sodium polypectate and silver ion in amounts of 100-400 ppm and 13-250 ppm, respectively (for example, see claim 1), or 0.01-0.04% and 0.0013-0.025%, respectively. These amount ranges overlap those of the claimed invention, and one

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skilled in the art would be motivated to manipulate the amounts of said biocidal agents from within said ranges by routine experimentation, in order to optimize the biocidal activity of the composition.

**9. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Van Leuven (US Patent 4,267,168) in view of Bringloe (US Patent 4,765,478) as applied to claims 12, 13, 16, and 18-22 above, and further in view of Hardy (US Patent 4,981,686).**

Claim 14 of the claimed invention is drawn to the method as claimed in claim 13, wherein the organic substance with a lubricant effect comprises a natural or synthetic oil, fat or wax.

The invention of the combined references is delineated above (see paragraph 5).

The invention of the combined references does not specifically teach the presence of an organic lubricant which is a natural or synthetic oil, fat or wax.

Hardy teaches a vaginal lubricant which soothes vaginal tissue (col. 1, lines 55-65). The composition comprises a preferable combination of lubricants selected from petrolatum, coconut oil, lanolin, mineral oil, and stearyl alcohol (col. 2, lines 32-36). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to add a natural or synthetic oil, fat or wax to the composition taught by the invention of the combined references; thus arriving at the claimed invention. One skilled in the art would have been motivated to do so because the addition of lubricant(s) such as petrolatum, coconut oil, lanolin, mineral oil, and/or

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stearyl alcohol provides the benefits of desired lubricity without being irritating, as taught by Hardy (col. 2, lines 32-36). Additionally, it is prima facie obvious to combine two compositions, each of which is taught by the prior art, to be useful for the same purpose (in this case, as lubricants), in order to form a third composition to be used for the very same purpose. See MPEP 2144.06 One would reasonably expect success from the addition of lubricants as taught by Hardy to the composition taught by the invention of the combined references because both references are drawn to lubricant compositions which are applied to vaginal tissue.

**10. Claims 12, 13, 15, 16, 18-20, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kasahara et al (US Patent 3,971,848) in view of Bringloe (US Patent 4,765,478).**

The claimed invention is drawn to a method for reducing the frictional force between an item to be delivered and the birth canal of the mother in human vaginal child birthing, which comprises introducing a composition comprising a physiologically acceptable organic lubricant and no alkali metal salts of metaphosphates, wherein the composition is in the form of a paste, gel, cream, suppository, or foam, in an effective amount into the birth canal of the woman (see claim 12).

Kasahara et al teach a composition having lubricating property comprising fucoidin and alginic acid (abstract) and does not contain alkali metal metaphosphates. The composition may be used to lubricate the birth canal in human bodies to facilitate



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the delivery of the fetus (col. 5, lines 16-32). The composition may be optionally mixed with carboxymethyl cellulose (col. 5, lines 39-42).

Kasahara et al do not specifically teach that the composition is in the form of a gel.

Bringloe teaches that carboxymethyl cellulose is a known gelling agent in topical compositions (see col. 3, lines 46-53).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to formulate the compositions taught by Kasahara et al in the form of a gel; thus arriving at the claimed invention. Carboxymethyl cellulose is a known gelling agent, as taught by Bringloe, and thus one skilled in the art would reasonably expect that the use of carboxymethyl cellulose in a composition would result in the composition being in the form of a gel, especially in light of the fact that the lubricant is "mucous and thready" (col. 2, lines 7-8), which would favor a gel composition. One skilled in the art would have been motivated to add carboxymethyl cellulose to the composition in order to optimize the viscosity, as taught by Kasahara et al, since a thicker (i.e., more viscous) composition would result in the lubricant composition adhering more to the wall of the birth canal, thus providing a greater lubricant effect. One would reasonably expect success from the use of carboxymethyl cellulose as a gelling agent (as taught by Bringloe) in the composition taught by Kasahara et al because Kasahara et al teach that carboxymethyl cellulose may be added to the composition.

Regarding claim 13, Kasahara et al teach that the composition comprising fucoidin and alginic acid has a lubricating property, and therefore an organic substance (i.e., fucoidin/alginic acid) brings about a lubricant effect in the composition, or confers a lubricant effect through formulation of the composition.

Regarding claim 15, Kasahara et al teach that the fucoidin lubricant is a polymer (col. 2, lines 54-59).

Regarding claim 16, Kasahara et al teach that the composition may comprise carboxymethyl cellulose, a known gelling agent, and therefore would form a gel.

Regarding claim 18, Kasahara et al teach that the composition is in the form of a solution (see Examples).

Regarding claim 19, Kasahara et al teach that the lubricant of fucoidin/alginic acid is present in amounts of 72.2-85.1% (see Examples).

Regarding claims 20 and 22, Kasahara et al teach that the composition may include an antiseptic (col. 5, lines 48-49), which would prevent infection.

**11. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kasahara (US Patent 3,971,848) in view of Bringloe (US Patent 4,765,478) as applied to claims 12, 13, 15, 16, 18-20, and 22 above, and further in view of Hardy (US Patent 4,981,686).**

Claim 14 of the claimed invention is drawn to the method as claimed in claim 13, wherein the organic substance with a lubricant effect comprises a natural or synthetic oil, fat or wax.

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The invention of the combined references is delineated above (see paragraph 7).

The invention of the combined references does not specifically teach the presence of an organic lubricant which is a natural or synthetic oil, fat or wax.

Hardy teaches a vaginal lubricant which soothes vaginal tissue (col. 1, lines 55-65). The composition comprises a preferable combination of lubricants selected from petrolatum, coconut oil, lanolin, mineral oil, and stearyl alcohol (col. 2, lines 32-36).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to add a natural or synthetic oil, fat or wax to the composition taught by the invention of the combined references; thus arriving at the claimed invention. One skilled in the art would have been motivated to do so because the addition of lubricant(s) such as petrolatum, coconut oil, lanolin, mineral oil, and/or stearyl alcohol provides the benefits of desired lubricity without being irritating, as taught by Hardy (col. 2, lines 32-36). Additionally, it is prima facie obvious to combine two compositions, each of which is taught by the prior art, to be useful for the same purpose (in this case, as lubricants), in order to form a third composition to be used for the very same purpose. See MPEP 2144.06 One would reasonably expect success from the addition of lubricants as taught by Hardy to the composition taught by the invention of the combined references because both references are drawn to lubricant compositions which are applied to vaginal tissue (which is a part of the birth canal).

**12. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kasahara (US Patent 3,971,848) in view of Bringloe (US Patent 4,765,478) as**

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**applied to claims 12, 13, 15, 16, 18-20, and 22 above, and further in view of Van Leuven (US Patent 4,267,168).**

Claim 21 of the claimed invention is drawn to the method as claimed in claim 20, wherein the amount of active pharmaceutical ingredients is from 0.0001 to 10% by weight (see claim 21).

The invention of the combined references is delineated above (see paragraph 7). Kasahara et al teach that an antiseptic may be present in the composition (col. 5, lines 48-49).

The invention of the combined references is silent with respect to the amount of antiseptic.

Van Leuven teaches that, in compositions used as a lubricant during delivery at the time of birth, it is known to use the biocidal agents sodium polypectate and silver ion in amounts of 100-400 ppm and 13-250 ppm, respectively (for example, see claim 1), or 0.01-0.04% and 0.0013-0.025%, respectively.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to use biocidal agents (i.e., antiseptics) in amounts taught by Van Leuven in the composition of the combined references; thus arriving at the claimed invention. One skilled in the art would have been motivated to use said amounts because Van Leuven fairly teaches and suggests useful amounts of biocidal agents in lubricant compositions used during delivery at the time of birth. Furthermore, said amounts overlap those of the claimed invention, and one skilled in the art would be

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motivated to manipulate the amounts of said biocidal agents from within said ranges by routine experimentation, in order to optimize the antiseptic activity of the composition.

**13. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kasahara (US Patent 3,971,848) in view of Bringloe (US Patent 4,765,478) as applied to claims 12, 13, 15, 16, 18-20, and 22 above, and further in view of JP 46-24256 (English abstract submitted herewith).**

Claim 23 of the claimed invention is drawn a method for reducing the frictional force between an item to be delivered and the birth canal of the mother in human vaginal child birthing, which comprises introducing a composition comprising a physiologically acceptable polyacrylic acid lubricant and no alkali metal salts of metaphosphates, wherein the composition is in the form of a paste, gel, cream, suppository, or foam, in an effective amount into the birth canal of the woman (see claim 23).

The invention of the combined references is delineated above (see paragraph 7). Kasahara et al teach that the composition may also comprise sodium polyacrylate (col. 5, lines 40-41).

Kasahara et al do not teach that the sodium polyacrylate is present as a lubricant.

JP '256 teaches that sodium polyacrylate is useful as a lubricant during birth (see abstract).

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It would have been obvious to a person having ordinary skill in the art at the time the invention was made to use sodium polyacrylate as a lubricant in the composition of the combined references; thus arriving at the claimed invention. One skilled in the art would be motivated to do so because JP '256 fairly teaches and suggests that sodium polyacrylate is useful as a lubricant during birth, and therefore one skilled in the art would reasonably expect the sodium polyacrylate in the composition of Kasahara et al to function as a lubricant. Furthermore, while JP '256 teaches that the lubricant is useful in veterinary applications, Kasahara et al teach that lubricants useful in veterinary applications would be equally effective in human bodies as well (see col. 5, lines 16-32). One would reasonably expect success from the use of sodium polyacrylate in the composition of the combined references because Kasahara et al teach that sodium polyacrylate may be present in the composition, and JP'256 teaches that sodium polyacrylate is useful as a lubricant.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BARBARA FRAZIER whose telephone number is (571)270-3496. The examiner can normally be reached on Monday-Thursday 9am-4pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571)272-0614. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BSF

/Sharmila Gollamudi Landau/  
Supervisory Patent Examiner, Art Unit 1611